REMARKS

The specification has been amended to correct various typographical, stylistic, and idiomatic informalities.

Applicant has amended claims 20, 22, and 23, cancelled claims 12-19, and added new claims 24-37.

In the action of July 10, 2001, the Examiner rejected claims 12-19 under 35 U.S.C. §102(b) over U.S. Patent No. 4,950,278 to Sachse et al. To expedite prosecution, we address the Sachse et al. reference in view of newly added claims 24-37, of which claims 24 and 36 are in independent form.

New claim 24 relates to a surgical endoscopic cutting assembly including a housing assembly having fitted therein a viewing channel and including a receiving part, and a cutter received within the receiving part. The cutter defines a suction channel and the housing assembly defines a suction channel. The cutter suction channel is for discharging fluid and cut tissue, while the housing assembly suction channel is configured and arranged for discharging substantially only fluid. An opening in fluid communication with the housing assembly suction channel extends through a wall of the housing assembly in a distal portion of the housing assembly.

New claim 36 relates to a surgical instrument including a mechanical cutting implement configured to cut tissue, a first member coupled to the cutting implement and defining a first channel configured and arranged relative to the cutting implement for removing fluid and cut tissue from a surgical site, and a second member coupled to the cutting implement and defining a second channel configured and arranged relative to the cutting implement such that substantially only fluid is discharged form the surgical site through the second channel. An opening in fluid communication with the second channel extends through a wall of the second member in a distal portion of the second member.

Sachse et al. does not describe or suggest a surgical instrument having one channel for removing fluid and cut tissue, and another channel configured and arranged for discharging substantially only fluid. Sachse et al. describes an endoscope for removal of tissue including

ducts 46 and 47. Fluid is delivered through duct 47 and discharged through duct 46 (see, e.g., Sachse et al., col. 3, lines 27-38, or fluid is delivered through duct 46 and discharged through duct 47 (see, e.g., Sachse et al., col. 3, lines 39-48). As stated at col. 3, lines 49-53 of Sachse et al., both ducts 46 and 47 of Sachse et al. are configured to remove both fluid and cut tissue:

> In both embodiments, the operating area of the instrument 7 is constantly supplied with clean flushing liquid and the turbid liquid that occurs there and is mixed with tissue parts, stone particles, blood, etc. is also continuously sucked off.

Thus, the endoscope of Sachse et al. does not include a channel configured and arranged to remove substantially only fluid.

Therefore, applicant submits that new claims 24 and 36, and their dependent claims, are patentable over Sachse et al.

Attached is a marked-up version of the changes being made by the current amendment.

Applicant asks that all claims be allowed. Enclosed is a check for the Petition for Extension of Time fee. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: November 8, 2001

Phyllis K. Kristal
Reg. No. 38,524

Fish & Richardson P.C.
601 Thirteenth Street, NW
Washington, DC 20005
Telephone: (202) 783-5070
Facsimile: (202) 783-2331

Version with markings to show changes made

In the Specification:

The paragraph beginning at page 1, line 2 has been amended as follows:

[Surgical endoscopic cutting device, and method for its use.]

Field of the Invention

The present invention relates to a surgical endoscopic cutting device [according to the preamble of Claim 1].

The paragraph beginning at page 1, line 6 has been amended as follows:

Background of the Invention

[Such a] Surgical cutting [device is] devices are generally known and [is] used for the removal of hard and/or soft tissue, such as in the vicinity of the knee joint. Such [a] cutting [device is] devices are used in, for example, a joint cavity, where [everything] they can be guided endoscopically by separately inserting a viewing device [consisting of] having a light source and an observation [part] portion. Such operations are successfully used in organs and joints lying not too deep underneath the skin.

The paragraph beginning at page 1, line 12 has been amended as follows:

When operations are being carried out on organs lying deeper [down], other techniques are currently used. If, for example, tissue has to be removed from the uterus, prostate, or urinary bladder, such as mucous membrane or other [parts] tissues, it was customary until now to use a so-called "loop." This is a loop-shaped cutting wire which is brought to a first potential, while the wall of the uterus is brought to a second, different potential. Tissue is removed by moving the loop along the [part of the] uterus wall [concerned]. In order to be able to carry out such an operation, it is necessary to dilate the uterus[, and this] . Dilation is carried out by introducing a

fluid. In order to maintain the effect of the potential difference, [it is necessary for such a fluid not to be current-conducting] a non-conducting fluid is used, [. An] for example [of this is] a 5% sorbitol solution. Because wounds are caused during the treatment described above, a good part of this fluid is resorbed into the patient's bloodstream (by way of the uterus). This can lead to highly dangerous electrolyte displacements. It has been found that the tissue can be removed more easily by working with a high-frequency monopolar electric current, but there is a risk of [such a] high-frequency electric current leading to internal and external burns. The loop [used] is generally fitted on [a working element with handle on] an endoscope and [is] moved [in a] back and forth [movement] along the uterus wall [together] with the endoscope. The tissue cut off during this treatment has to be removed [separately] from the uterus, which considerably extends the duration of the operation[, and in addition] . Furthermore, the doctor has to check that all detached material actually has been removed.

The paragraph beginning at page 2, line 1 has been amended as follows:

This means that such operations are very time-consuming and require the surgeon to [take a large number of steps] repeatedly [moving] move the device back and forth[, which are] . This is tiring [in the long run] and [are] consequently [found] difficult to learn. Moreover, the patient has to be monitored continually during the operation, in order to prevent the undesirable phenomena described above. It is not uncommon for such an operation to be broken off because the [side effects are such that the] patient's life is endangered by the side effects.

The paragraph beginning at page 2, line 7 has been amended as follows:

WO 96/11638 discloses a [device operating in a machining manner described above. In this case the cutting means, consisting of] cutter including a hollow stem and a cutting head[, are] accommodated inside [the] a rigid housing. This rigid housing likewise contains a viewing channel with the necessary [optics.USA-A-5,195,541] optics. USA-A-5,195,541 [from which the preamble of claim 1 has been delimited discloses] describes a laproscopic discectomy

apparatus. For a laproscopic method it is essential to inflate the related cavity [through] using gas. The gas feed is discontinuous and has no effect on viewing of the operation [side] site.

The paragraph beginning at page 2, line 9 has been amended as follows:

Fluid is introduced by way of [the] a space between the stem and the rigid housing and discharged together with the detached tissue through the hollow stem of the [cutting means] cutter.

The paragraph beginning at page 2, line 19 has been amended as follows:

This device could be satisfactory for the removal of tissues from certain body cavities, such as from the bladder. However, in the case of other body cavities, it is necessary to "blow up" the cavity before [the] treatment can be carried out. An example of this is the uterus, in [the case of] which it is important that the amount of enlargement of [such an] the organ [is] be accurately controlled. The irregular discharge of fluid through the hollow stem of the [cutting means] cutter, [partly] caused partly by the irregular release of tissue, means that it cannot be guaranteed that the pressure inside the cavity [concerned has been] is accurately controlled.

The paragraph beginning at page 2, line 29 has been amended as follows:

Summary of the Invention

The object of the present invention is to provide a device [by means of] which can perform such a treatment [is possible after all]. [This object is achieved in the case of a device of the type described above by the characterizing measures of Claim 1.]

The paragraph beginning at page 2a, line 1 has been amended as follows:

[By means of] According to the invention, a further outlet channel is provided, the function of which [channel] is independent of whether or not detached tissue has been released. In other words, a regular discharge of fluid can occur [by way of] through this further outlet channel. Since only a minor part of the fluid is now discharged [by way of] through the outlet, in which there are detached pieces of tissue, the pressure inside the body cavity [concerned] can be regulated and controlled accurately. This makes it possible [also] to remove undesired tissue from cavities such as the uterus. The [application field of the technology for] applicability of the removal of tissues by cutting is consequently considerably increased.

The paragraph beginning at page 3, line 1 has been amended as follows:

[This] The further outlet channel described above is formed [can be achievedin that] by an insertion tube [is] fitted around the endoscopic device. This insertion tube serves to clear a space for the endoscopic device. For this purpose, the front side of the insertion tube can be provided [at the front side] with an insertion mandrel, which is removed after the positioning of the insertion tube and replaced by the endoscopic device described above. In this case the further outlet channel can be defined between the endoscopic device and the insertion tube.

The paragraph beginning at page 3, line 9 has been amended as follows:

In the case of such a construction it is desirable for a [coupling means] coupler to be present[, in order] to provide a coupling between the rigid housing and the insertion tube described above.

The paragraph beginning at page 3, line 12 has been amended as follows:

Discharge of the tissue material which has been detached can be achieved either by making the stem on which the cutting elements are fitted hollow, or by fitting a protective tube [surrounding] around the [cutting means] cutter. Such a protective tube can also be used without the space between protective tube and stem serving as an outlet channel. This means that the

[cutting means] cutter can be designed as a separate unit which can be coupled to the rigid housing, which has advantages in particular [in the field] for purposes of sterilization[, for] . Namely, the device [according to the invention] can then be detached in a [particularly] simple way.

The paragraph beginning at page 3, line 21 has been amended as follows:

For the removal of tissue [in] from a uterus it is essential for the rigid housing to have a length which is sufficient to reach all tissue parts, i.e. a length of at least 30 cm.

The paragraph beginning at page 3, line 24 has been amended as follows:

The observation part of the device described above [comprises] includes a light channel in the housing, provided near one end [provided] with a lens and near the other end [provided] with an observation [means] mechanism. The latter can [consist of] include an eyepiece or a connection for a camera[,] so that the surgeon can carry out the operation [in question] using a monitor[,] and others can possibly look at the same time.

The paragraph beginning at page 3, line 30 has been amended as follows:

The cutting elements described above can [comprise all] include any cutting [elements] element known in the prior art. In other words, a cutting head with cutting faces can be used, but it is also possible to use constructions with teeth, meshing with the protective [means] tube or otherwise. In the latter instance, the protective tube is preferably provided with a lateral opening through which a part of the cutting elements extends[,] so that on each revolution, part of the tissue is removed and can be discharged directly through the interior of the drive/discharge tube of the [cutting means] cutter.

The paragraph beginning at page 4, line 7 has been amended as follows:

According to a further embodiment of the method, an outlet and a further outlet are present, and the pressure inside the body cavity [concerned] is regulated by metering the quantity of fluid which moves through [that] the further outlet. The insertion of the surgical endoscopic cutting device is preferably carried out in the manner described above [by means of] using an insertion mandrel and insertion tube.

The paragraph beginning at page 4, line 13 has been amended as follows:

Brief Description of the Drawings

The invention will be explained in greater detail below with reference to an exemplary embodiment shown in the [drawing] drawings, in which:

Fig. 1 shows the endoscopic cutting device according to the invention in the assembled state, in side view and partially in section;

Fig. 1a shows the viewing/receiving part of the cutting device of Fig. 1 in section along the line Ia-Ia;

Fig. 2 shows a side and partially cut-away view of the viewing/receiving part of the cutting device [according to] of Fig. 1[, in side view and partially in section (Fig. la)];

Fig. 3 shows a partially cut-away perspective view of the device [according to] of Fig. 1 [in perspective view], with the insertion end [on an] enlarged [scale];

Fig. 4 shows a partially sectional side view of the [cutting means] cutter of the cutting device [according to] of Fig. 3[, in side view and partially in section];

Fig. 5 shows [a detail of] a variant of the [cutting means] cutter shown in Fig. 4; and

Fig. 6 shows [the] an insertion mandrel according to the invention.

The paragraph beginning at page 4, line 25 has been amended as follows:

Detailed Description

The endoscopic cutting device according to the invention is indicated in its entirety by 1 in Fig. 1. It comprises a viewing/receiving part 3, which is shown in Fig. 2, a cutting part 2,

which is shown in greater detail in Figs. 4 and 5, and an insertion mandrel, which is shown in Fig. 6.

The paragraph beginning at page 5, line 1 has been amended as follows:

The [distance from the part to be inserted into the patient, i.e. the] length of the actual outer tube 4, is indicated by A[,] and is more than 30 cm.

The paragraph beginning at page 5, line 4 has been amended as follows:

Fig. 4 shows details of the [cutting means] cutter or the cutting part 2, which is composed of a protective tube 16[,] inside of which a drive/suction tube 17 is fitted. Near the working end, tube 17 is provided with teeth 19 which mesh with teeth 18 provided in an opening 26 in the end part of protective tube 16. Near the other end, drive/suction tube 17 is provided with a coupling 20, which can be connected at one end to a rotating drive motor 21, not shown in detail, and at the other end is provided with an opening 22 through which fluid and removed material can be discharged by way of suction tube 17 to the discharge hose 23. [Pressure-regulating means] A pressure regulator can be present in this discharge hose 23, which is connected to a vacuum source.

The paragraph beginning at page 5, line 14 has been amended as follows:

In Fig. 1 the insertion part is [also] indicated by 27. This insertion part is composed of an insertion tube 28 which is provided with openings 29 at one end and near the other end [away from the insertion end], the insertion part 27 is provided with a bayonet connection 30 and an outlet 31. Insertion tube 28 is designed in such a way that [the rigid housing] tube 4 can be fitted therein, as shown in Figs. 1 and 3, while it is also possible to fit insertion mandrel 40, provided with stem 41 and mandrel 42, in insertion tube 28.

The paragraph beginning at page 5, line 21 has been amended as follows:

The construction described above has an inlet 38 for fluid[, which inlet] . Inlet 38 extends to channel 14 (Fig. la), i.e. the space bounded between the outer tube 4 and the protective tube 16 and 36, respectively from Figs. 4 or 5. A shut-off valve 39, which is connected to channel 14, is present, while the further outlet is indicated by 31. A discharge hose 23 for tissue and fluid is shown. During the removal of tissue, with a substantially continuous supply of fluid through inlet 38, some of the fluid will be discharged through outlet 23. This relatively small amount will be mixed with a mixture released during the cutting operation. Most of the fluid will be discharged through the further outlet 31. This discharge is unimpeded and occurs through openings 29. Pressure variations occurring [through] due to the presence or absence of removed tissue [and through] in channel 17 (Fig. 4) [being shut off or otherwise] have little or no influence on the pressure inside the body cavity [concerned,] owing to the presence of the further outlet 31.

The paragraph beginning at page 5, line 35 has been amended as follows:

If the device is to be inserted into, for example, a uterus, insertion mandrel 40 will first be inserted, with shut-off valve 39 open, into insertion tube 28 with bayonet 30. This assembly is then placed in the uterus in a relatively simple manner[, through] due to the shape of mandrel 42. Mandrel 42 is then removed by [manipulation on] manipulating stem 41, and the construction shown in Fig. 2 is placed in tube 28. Connection is made here to bayonet 30. The cutting action can then begin[,] after the uterus has been dilated [first] by the introduction of fluid. This fluid can [comprise] be a physiological flushing and distension fluid, such as a physiological salt solution (NaCl 0.9%). In the event of the (unavoidable) resorption of [these] the physiological [fluids] fluid into the blood, electrolyte [displacements] displacement, with fatal consequences for the patient, will not occur. Owing to the absence of electrical current, the burns described above are also ruled out.

The paragraph beginning at page 6, line 10 has been amended as follows:

By switching on motor 21, tube 17 is set in rotation and teeth 19 move regularly along cutting edge 18 of protective tube 16[,] which remains stationary. While they are moving along each other and picking up tissue material between them, a cutting, detaching action on the tissue material is occurring. [, and this] The cut, detached material is removed through the interior of tube 17 and outlet 23.

The paragraph beginning at page 6, line 19 has been amended as follows:

Through the use of a continuous flow system, a constantly clear view is obtained for the observer[,] even if blood and/or mucous is/are in the mixture. Moreover, the pressure can be [kept constantly] maintained as low as possible, in order to prevent intravasation.

The paragraph beginning at page 6, line 23 has been amended as follows:

Fig. 5 shows a variant of the end of the [cutting means] cutter. The [cutting means] cutter or cutting part are indicated in their entirety by 32. The protective tube is indicated by 36 and is bevelled near the end. The drive/suction tube is indicated by 37 and provided with a cutting head near the end. In this embodiment, there is either no interaction between cutting head 35 and protective tube 36, or [it occurs] head 35 and tube 36 interact near the edge of tube 36, which is adapted for that purpose by grinding.

The paragraph beginning at page 6, line 30 has been amended as follows:

It [will be] is understood that such cutting elements can be designed in [all ways] any way known in the prior art.

The paragraph beginning at page 6, line 32 has been amended as follows:

These and further modifications are considered to lie within the scope of the present application [and are] , to be immediately obvious to the person skilled in the art after reading [of]

the description, and to lie within the scope of the appended claims. For instance, it is possible to effect the supply of working fluid and the discharge of cleaning material in another way, i.e., to arrange the interior of housing 4 slightly differently. Furthermore, the method described above can be used for the removal of other tissue material, such as prostate tissue through the urethra, or for the removal of tissue from the wall of the urinary bladder.

In the Claims:

Claims 12-19 have been cancelled.

Claims 20, 22, and 23 have been amended as follows:

20. (Amended) Method for the removal of tissue from a body cavity, comprising

[the insertion of] inserting a device into said cavity for cutting and detaching said tissue,

introducing a fluid [being introduced] into said cavity,

discharging [which] fluid [is discharged again] with [the] detached tissue[, characterized in that the fluid is discharged along two paths,] along a first path [comprising said fluid and the detached tissue], and

discharging substantially only fluid along a [said] second path [substantially comprising fluid], said discharge along said second path being regulated [in such a way that the] to control pressure in said body cavity [is controlled].

22. (Amended) Method according to claim 20, in which [the insertion] inserting the device into said cavity [of said device] comprises

[the insertion of] inserting an insertion mandrel, and

[the removal thereof] removing the insertion mandrel [followed by] prior to [the insertion of] inserting the [cutting means] device.

23. (Amended) Method according to claim 21, in which [the insertion] inserting the device into said cavity [of said device] comprises

[the insertion of] inserting an insertion mandrel, and

[the removal thereof] removing the insertion mandrel [followed by] prior to [the insertion of] inserting the [cutting means] device.

New claims 24-37 have been added.

In the Abstract:

The abstract of the disclosure has been amended as follows:

Abstract of the Disclosure

[Surgical] A surgical endoscopic cutting device[. The latter consists of cutting means comprising] includes cutting elements fitted in a protective tube. [The cutting elements are motor-driven, the assembly comprising the cutting means being placed in a device which is also provided with a viewing device, in order to permit observation of a treatment. The length of the housing inserted into the patient's body is at least 30 cm.] The device has an inlet for fluid, a discharge outlet for tissue and fluid, and a further outlet that discharges most of the fluid.